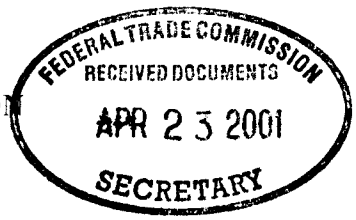
UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION



In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
Upsher-Smith Laboratories, a corporation,	)	
and	)	
American Home Products Corporation, a corporation.	)	

ANSWER OF AMERICAN HOME PRODUCTS CORPORATION

In 1996, Schering-Plough Corporation (Schering) sued ESI Lederle (ESI), now a business unit of an American Home Products Corporation (AHP) subsidiary, for patent infringement. Schering alleged that ESI's Abbreviated New Drug Application (ANDA) for a generic potassium chloride product infringed Schering's patent 4,863,743 ('743 patent). In 1998, following a hearing in which the Court implied that ESI's chances of success were not strong, ESI, AHP, and Schering entered into a settlement agreement. The settlement agreement was achieved with the active involvement of the Court, through the Court's designated Magistrate Judge. As a result of the settlement, the Court dismissed the patent litigation.

Under the terms of settlement, ESI obtained a royalty-free license to market its generic, allegedly infringing product beginning in January 2004, nearly three years before Schering's patent was due to expire in September 2006. Due to the effect of a previous agreement between Schering and Upsher-Smith Laboratories (Upsher), combined with

the provisions of the Hatch-Waxman Act, the earliest time at which ESI could otherwise have begun to market its product, in the unlikely event that it was held not to have infringed Schering's patent, would have been March 2002. By entering into the settlement agreement, the parties insured the entry of ESI's generic competition well before expiration of Schering's patent; in contrast, had the litigation continued, it was more likely than not that ESI would not have been able to begin marketing its product at any time before patent expiration.

The Complaint alleges that the parties' settlement agreement constitutes an unreasonable restraint of commerce, conspiracy to monopolize, and unfair method of competition, in violation of Section 5 of the FTC Act. AHP denies these allegations. AHP did not violate Section 5 of the FTC Act or any other antitrust law. Contrary to the Commission's press release announcing issuance of the Complaint, the case against AHP does not involve any "illegal payments to delay entry of generic products into the U.S. market." ESI, the generic product manufacturer, was not the net recipient of the value that flowed in the parties' settlement agreement -- Schering was. And, particularly because ESI was not going to be the first (or even second or third) company to sell a generic version of Schering's drug, it would not have been rational for Schering to pay ESI to delay its entry. AHP's actions were not intended to have, did not have, and were not likely to have, any adverse effect on competition. The settlement agreement insured that ESI would be able to offer its competing product before patent expiration and advanced the public interest in settlement of protracted and burdensome litigation. The procompetitive benefits of the agreement far outweigh any alleged anticompetitive effect. The Commission should defer to the judgment of the federal judge who accepted this

settlement as a proper means of resolving the dispute before him.

AHP answers each of the corresponding numbered paragraphs of the Complaint, based on personal knowledge as to its own actions and on information and belief as to all other matters, as follows:

1. AHP admits, upon information and belief, that Schering's K-Dur 20 product is used to treat patients who suffer from insufficient levels of potassium, a condition that can lead to serious cardiac problems. AHP denies all the other allegations of Paragraph 1 of the Complaint. To the extent that the allegations of Paragraph 1 concern the agreement between Schering and Upsher, the profitability of Schering's K-Dur 20 product, or the intent and purpose of Schering in entering any of its agreements, AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations.

2. AHP denies the allegations of Paragraph 2 and avers that, as to it, the allegations are inconsistent with other allegations of the complaint. In particular, given the fact alleged in paragraph 29 that "at all times relevant herein, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked," and the fact alleged in paragraph 66 that the effect of the settlement between Schering and Upsher-Smith has been to delay "the entry of competition from other generic manufacturers [such as ESI] until March 2002," there is no basis for an allegation that there has been any consumer injury as of the date of the complaint or at any date prior to March of 2002 by virtue of the settlement between AHP, ESI, and Schering.

3. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 and such allegations are therefore denied.

4. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 and such allegations are therefore denied.

5. AHP admits that it is a corporation organized and existing under the laws of Delaware with its principal place of business at Five Giralda Farms, Madison, New Jersey. AHP further admits that AHP engages in the discovery, development and marketing of brand name and generic drugs, as well as "over-the-counter" medications. In all other respects, AHP denies the allegations of Paragraph 5 of the Complaint.

6. AHP avers that ESI is a business unit of Wyeth-Ayerst Pharmaceuticals, Inc., a subsidiary of AHP. AHP admits that ESI engages in the research, manufacture, and sale primarily of generic drugs. In all other respects, AHP denies the allegations of Paragraph 6 of the Complaint.

7. AHP admits the allegations of Paragraph 7 of the Complaint.

8. The allegations of Paragraph 8 of the Complaint attempt to state a legal conclusion and therefore no response from AHP is required. To the extent a response is required, AHP denies the allegations of Paragraph 8 of the Complaint.

9. The allegations of Paragraph 9 of the Complaint attempt to state a legal conclusion and therefore no response from AHP is required. To the extent a response is required, AHP denies the allegations of Paragraph 9 of the Complaint.

10. The allegations of Paragraph 10 of the Complaint attempt to state a legal conclusion and therefore no response from AHP is required. To the extent a response is required, AHP admits the allegations of Paragraph 10 of the Complaint.

11. The allegations of Paragraph 11 of the Complaint attempt to state a legal conclusion and therefore no response from AHP is required. To the extent a response is

required, AHP denies the allegations of Paragraph 11 of the Complaint.

12. The allegations of Paragraph 12 of the Complaint attempt to state a legal conclusion and therefore no response from AHP is required. To the extent a response is required, AHP admits the allegations of Paragraph 12 of the Complaint.

13. AHP admits the allegations of Paragraph 13 of the Complaint.

14. The allegations of Paragraph 14 of the Complaint attempt to state a legal conclusion and therefore no response from AHP is required. AHP respectfully directs the Court to 21 U.S.C. 355(j)(5)(B)(iii) for the applicable provision of law. To the extent a response is required, AHP denies the allegations of Paragraph 14 of the Complaint.

15. The allegations of Paragraph 15 of the Complaint attempt to state a legal conclusion and therefore no response from AHP is required. AHP respectfully directs the Court to 21 U.S.C. 355(j)(5)(B)(iv) for the applicable provision of law. To the extent a response is required, AHP denies the allegations of Paragraph 15 of the Complaint.

16. The allegations of Paragraph 16 of the Complaint attempt to state a legal conclusion and therefore no response from AHP is required. At all times relevant herein, FDA regulations provided that an ANDA first filer remained entitled to the 180-day Exclusivity Period even if it were to lose its patent litigation with the patent holder. To the extent a response is required, AHP denies the allegations of Paragraph 16 of the Complaint.

17. AHP avers that generic entry by the first generic entrant generally leads to a significant erosion of the branded drug's market share and unit and dollar sales within the first year. In all other respects, AHP denies the allegations of Paragraph 17 of the Complaint.

18. AHP admits the allegations of Paragraph 18 of the Complaint.

19. AHP admits the allegations of Paragraph 19 of the Complaint.

20. AHP admits that the relevant geographic market to evaluate the conduct of AHP is the United States. To the extent that the other allegations of Paragraph 20 of the Complaint concern the agreement between Schering and Upsher, AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations and such allegations are therefore denied.

21. AHP denies the allegations of Paragraph 21 of the Complaint.

22. AHP admits the allegations of Paragraph 22 of the Complaint.

23. AHP denies the allegations of Paragraph 23 of the Complaint.

24. AHP denies the allegations of Paragraph 24 of the Complaint.

25. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 25 of the Complaint and such allegations are therefore denied.

26. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 26 of the Complaint and such allegations are therefore denied.

27. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 27 of the Complaint and such allegations are therefore denied.

28. AHP does not respond to the allegations concerning the requirements of FDA approval for NDAs and ANDAs because such allegations attempt to summarize matters of law and no response is therefore needed. In all other respects, AHP is without

knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 28 of the Complaint and such allegations are therefore denied.

29. AHP admits the allegations of Paragraph 29 of the Complaint with respect to the allegations against AHP.

30. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 30 of the Complaint and such allegations are therefore denied.

31. AHP admits that Schering manufactures and markets two extended-release microencapsulated potassium chloride products. AHP is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 31 of the Complaint and such allegations are therefore denied.

32. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 32 of the Complaint and such allegations are therefore denied.

33. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 33 of the Complaint and such allegations are therefore denied.

34. AHP admits the allegations of Paragraph 34 of the Complaint.

35. AHP avers that the '743 patent speaks for itself and otherwise denies the allegations of Paragraph 35 of the Complaint.

36. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 36 of the Complaint and such allegations are therefore denied.

37. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 37 of the Complaint and such allegations are therefore denied.

38. AHP admits that Upsher's ANDA was the first for a generic version of K-Dur 20 and that Upsher submitted a Paragraph IV Certification with this ANDA. AHP is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 38 of the Complaint and such allegations are therefore denied.

39. AHP admits that Schering sued Upsher for patent infringement in the United States District Court for the District of New Jersey. AHP is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 39 of the Complaint and such allegations are therefore denied.

40. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 40 of the Complaint and such allegations are therefore denied.

41. AHP admits to the allegations of Paragraph 41 of the Complaint.

42. AHP admits to the allegations of Paragraph 42 of the Complaint.

43. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 43 of the Complaint and such allegations are therefore denied.

44. AHP admits, upon information and belief, that Schering and Upsher agreed to settle their litigation. AHP is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 44 of the Complaint and such allegations are therefore denied.

45. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 45 of the Complaint and such allegations are therefore denied.

46. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 46 of the Complaint and such allegations are therefore denied.

47. AHP admits that, if Upsher had prevailed in the patent infringement suit, the FDA would have been permitted to grant final approval to Upsher's generic version of K-Dur 20, allowing Upsher to offer generic competition to Schering. In all other respects, AHP denies the allegations of Paragraph 47 of the Complaint. At all times relevant to this lawsuit, FDA regulations provided that Upsher would remain entitled to the 180-day Exclusivity Period even if Schering had prevailed in the patent infringement suit.

48. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 48 of the Complaint and such allegations are therefore denied.

49. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 49 of the Complaint and such allegations are therefore denied.

50. AHP admits to the allegations of Paragraph 50 of the Complaint.

51. AHP denies that it submitted an ANDA to the FDA on December 29, 1995. AHP admits the remaining allegations of Paragraph 51 of the Complaint.

52. AHP denies the allegations of Paragraph 52 of the Complaint.

53. AHP admits that Schering sued ESI for patent infringement in the United States

District Court for the Eastern District of Pennsylvania on February 16, 1996, alleging that ESI's generic version of Schering's K-Dur 20 infringed Schering's '743 patent. AHP does not respond to the remaining allegations concerning statutory waiting provisions because such allegations attempt to summarize matters of law and no response is therefore needed. AHP respectfully directs the Court to 21 U.S.C. 355(j)(5)(B)(iii) for the applicable provision of law. To the extent a response is required, AHP denies the remaining allegations of Paragraph 53 of the Complaint

54. AHP admits that by the end of January 1998 ESI had reached an unenforceable agreement in principle to settle the patent litigation; the agreement in principle contemplated the drafting of a definitive agreement and approvals by each party.

55. AHP avers that the statement "or with any other generic version of K-Dur 20" is ungrammatical and lacks meaning in the context of Paragraph 55 and on that basis the allegations to which the statement relates are denied. AHP denies the remaining allegations of Paragraph 55 of the Complaint and avers that the tentative agreement reached between Schering, AHP, and ESI in January 1998 had no binding effect upon any of the parties. None of the obligations referred to in Paragraph 55 of the Complaint, therefore, were incurred by any of the parties as a result of the January 1998 tentative agreement. AHP avers that, pursuant to the final settlement reached in June 1998, Schering agreed to license ESI under patent '743 to market ESI's generic potassium product beginning on January 1, 2004 on a royalty free basis. AHP further avers that, pursuant to the June 1998 settlement agreement, AHP and ESI agreed not to file any additional ANDAs for generic potassium chloride products prior to September of 2006. AHP avers that, pursuant to the June 1998 settlement agreement, AHP and ESI agreed

not to conduct, sponsor, file or support a study of the bioequivalence of a potassium chloride product to K-Dur 20 prior to September 5, 2006. AHP does not understand what event the alleged "up front" payment is alleged to be in "front" of, and denies such allegation. Pursuant to the June 1998 agreement, Schering agreed to pay an additional $10 million in the event, and only in the event, that ESI succeeded in securing tentative FDA approval for its generic potassium chloride product prior to June 30, 1999. AHP further avers that, pursuant to the June 1998 settlement agreement, ESI and AHP agreed to license Schering to use ESI intellectual property to develop and market generic versions of two highly profitable products in Europe. AHP avers that, pursuant to this agreement, Schering agreed to pay ESI $6.3 million within 10 days of execution of the agreement and $8.7 million in seven installments to the year 2005.

56. AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 56 of the Complaint and such allegations are therefore denied.

57. AHP notes that there is no allegation in this paragraph that the licensed products were not worth the amount paid for them. AHP avers that the price paid was negotiated at arms' length and like any negotiated price was based on the amount that ESI was willing to accept and that Schering was willing to pay. In all other respects AHP denies the allegations of Paragraph 57.

58. AHP admits that, on June 19, 1998, Schering and ESI executed their final settlement agreement. AHP further admits that the patent litigation had previously been dismissed with prejudice but avers that the dismissal had been subject to modification or vacatur within 90 days of entry pursuant to Local Rule 41.1(b) of the Eastern District of

Pennsylvania. The parties had sought, and Judge DuBois had granted, an extension of the initial 90 day period. As a result, the rights of both parties to vacate the dismissal had been preserved and were operative at the time the definitive settlement was reached in June of 1998.

59. AHP admits the allegations of Paragraph 59 of the Complaint.

60. AHP admits the allegations of Paragraph 60 of the Complaint.

61. AHP admits, upon information and belief, that Andrx filed an ANDA for a generic version of Schering's K-Dur 20 in 1999. AHP is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 61 of the Complaint and such allegations are therefore denied.

62. AHP admits the allegations of Paragraph 62 of the Complaint.

63. AHP has no obligation to admit or deny Paragraph 63 to the extent it encompasses allegations about the agreement between Upsher and Schering, to which AHP was not a party. AHP denies the remaining allegations of Paragraph 63.

64. AHP has no obligation to admit or deny Paragraph 64 to the extent it encompasses allegations about the agreement between Upsher and Schering, to which AHP was not a party. AHP denies the remaining allegations of Paragraph 64.

65. AHP denies the allegations of Paragraph 65 of the Complaint.

66. AHP admits the allegations of Paragraph 66 except to the extent the allegations incorporate some undefined notion of relevant market and as to the assertion of (b) as to an alleged forfeiture effect should Schering have prevailed, which allegations are denied.

67. AHP denies the allegations of Paragraph 67 of the Complaint.

68. Paragraph 68 makes no allegations as to AHP and hence AHP has no obligation to

admit or deny. To the extent it has such an obligation, AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 68 of the Complaint and such allegations are therefore denied.

69. AHP denies the allegations of Paragraph 69 of the Complaint.

70. Paragraph 70 makes no allegations as to AHP and hence AHP has no obligation to admit or deny. To the extent it has such an obligation, AHP is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 70 of the Complaint and such allegations are therefore denied.

71. AHP denies the allegations of Paragraph 71 of the Complaint.

Except as specifically admitted and denied, AHP is without knowledge or information sufficient to admit or deny the allegations of the Complaint and on that basis denies them.

FIRST DEFENSE

The Complaint fails to state, in whole or in part, a claim against AHP upon which relief can be granted under § 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

SECOND DEFENSE

AHP's conduct was not intended to have, did not have, and is not likely to have any adverse effects on competition in any relevant market.

THIRD DEFENSE

Any provisions of the settlement agreement between AHP, ESI, and Schering that could possibly be construed as anticompetitive are ancillary to the settlement's primary purpose that was both lawful and procompetitive.

FOURTH DEFENSE

The procompetitive effects of the settlement agreement between AHP, ESI, and Schering outweigh any provisions of the settlement agreement that could possibly be construed as anticompetitive.

FIFTH DEFENSE

The settlement agreement between AHP, ESI, and Schering is immune from antitrust scrutiny by virtue of the *Noerr-Pennington* doctrine. The issuance of the complaint is improper because the conduct it attacks, the dismissal of the patent litigation pursuant to a settlement agreement, is an action taken by a United States Federal Judge acting pursuant to his Article III powers.

SIXTH DEFENSE

The proposed relief in the Complaint that is directed at the settlement agreement between AHP, ESI, and Schering is contrary to the public interest and sound public policy in that it interferes with and unduly hampers the proper maintenance, prosecution, and settlement of patent infringement litigation and the settlement of litigation generally. This proposed relief would reduce the value of patents, deter innovation, and undermine the public policies underlying the patent system. It would also deter innovation on the part of generic manufacturers. Without a realistic opportunity of settlement, the prospect of lengthy and expensive infringement litigation will greatly discourage potential generic manufacturers from making the investments necessary to develop generic products. Such a result would be inconsistent with the purposes of the Hatch-Waxman Act and contrary to the strong public policy in favor of settlements generally.

SEVENTH DEFENSE

The Complaint and the proposed relief directed at the settlement agreement

between AHP, ESI, and Schering are barred because they are inconsistent with and preempted by the statutory rights granted to Schering as holder of the '743 patent under the Patent Act, 35 U.S.C. § 271 *et seq.*

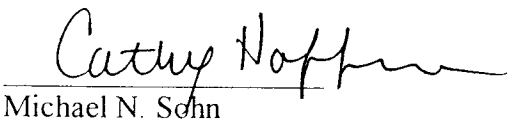
EIGHTH DEFENSE

AHP had legitimate business justifications for all of its conduct at issue in this matter.

WHEREFORE, respondent AHP demands judgment dismissing the Complaint with prejudice and with costs, and awarding such other and further relief as shall be deemed just and proper.

Dated: April 23, 2001

Respectfully submitted,



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a corporation,	)	Docket No. 9297
	)	
Upsher-Smith Laboratories,	)	
a corporation,	)	
	)	
and	)	
	)	
American Home Products Corporation,	)	
a corporation.	)	

CERTIFICATE OF SERVICE

I, Barbara H. Wootton, hereby certify that on April 23, 2001, I caused a true and correct copy of the *Answer of American Home Products Corporation* to be served upon the following persons by hand delivery or Federal Express:

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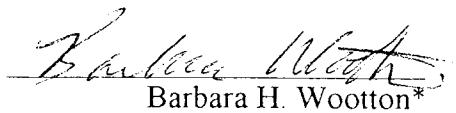

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*Admitted to the Maryland Bar only; practice supervised directly by active members of the D.C. Bar pending approval of application for admission to the D.C. Bar.